REMARKS

The Final Office action dated January 5, 2011 is acknowledged. The Applicants thank the Examiner for withdrawing the finality of the previous rejection. The Applicants also thank the Examiner for withdrawing the previous objection to claim 5 and the rejection of the claims under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,614,178 (Bloom, et al.) and under 35 U.S.C. 103(a) as being unpatentable over El-Bloom, et al. in view of U.S. Patent No. 4,666,441 (Andriola, et al.).

Claims 1-4, 6-10, 12-23, 25, 26 and 28 are pending in the instant application. Claims 2-4, 6-10, 14-23, 25 and 28 have been withdrawn and claims 1, 12-13 and 26 are rejected. By the present Final Office Action response, claims 1, 3, 13 and 20 have been amended, and claim 12 has been canceled. The subject matter of claim 12 has been incorporated into amended claim 1. In addition, claim 1 has been amended to recite that the transdermal therapeutic system contains said combination in a solid polymer matriz, such for which may be found in the substitute specification at paragraphs [000036] and [000039]. Claim 13 has been amended to depend from claim 1 rather than claim 12. Claim 3, which is considered withdrawn, has been amended just to correct a spelling error, i.e., "carbergoline" has been corrected to read "cabergoline." The corresponding changes have also been made in the specification, as noted above by the amended specification paragraphs.

Additional minor spelling changes have been made to the specification and claims, such as "bipreriden" or "bipreridene" to "biperiden," "benzatropine" to "benztropine" and "antagonists" to "agonists."

Reconsideration is respectfully requested in light of the arguments and amendments made herein. No new matter has been added.

Rejection of claims 1, 12-13 and 26 under 35 U.S.C. 103(a)

Claim 1 has been rejected as being unpatentable over U.S. Publication No. 2004/0013620 (Klose, et al.). The Examiner states in the Final Office action that Klose, et al. disclose transdermal drug delivery systems comprising a therapeutically effective amount of an anti-Parkinson agent and that suitable anti-Parkinson agents include levodopa and bornaprine. The Examiner acknowledges that Klose, et al. do not exemplify the combination of the two active agents, but argues that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected two components from a finite grouping of active agents which are useful for the same purpose to form a combination of active agents which is also useful for the same purpose. Therefore, the Examiner concludes that since the reference teaches that both levodopa and bornaprine are effective agents in the treatment of Parkinson's disease, it would have been obvious to one skilled in the art to combine them with the expectation that such a combination would be effective in the treatment of Parkinson's disease. In turn, the Examiner concludes that combining them flows logically from their having been individually taught in the prior art.

Claims 1 and 12 are rejected as being unpatentable over U.S. Publication No. 2007/0225379 (Carrara, et al.). The Examiner argues that Carrara, et al. disclose transdermal compositions which can be incorporated into patch devices, and that the compositions include components which have an effect on the central nervous system,

such as drugs to treat Parkinson's disease. The Examiner also states that examples of anti-Parkinson drugs disclosed include levodopa and bornaprine within a finite grouping of active agents and that mixtures of the disclosed agents are also disclosed as suitable for use. The Examiner further argues that the Carrara, et al. reference does not exemplify the combination of the two active agents, but that it would have been obvious to one of ordinary skill in the art at the time of the invention was made to have selected two components from a finite grouping of active agents which are useful for the same purpose to form a combination of active agents which is also useful for the same purpose. Therefore, the Examiner concludes that since the reference teaches that both levodopa and bornaprine are effective agents in the treatment of Parkinson's disease, it would have been obvious to combine them with the expectation that such a combination would be effective in the treatment of Parkinson's disease. In turn, the Examiner concludes that combining them flows logically from their having been individually taught in the prior art.

Claims 13 and 26 are rejected as being unpatentable over Carrara, et al., in view of U.S. Patent No. 4,666,441 (Andriola, et al.). The Examiner references the teachings of Carrara, et al. as discussed above and acknowledges that Carrara, et al. do not disclose the orientation of the transdermal device. The Examiner refers to the Andriola, et al. reference which discloses, according to the Examiner, a multi-compartmentalized transdermal patch. Therefore, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to have utilized the patch of Andriola, et al. because it is disclosed that the advantages of the patch allows one to flexibly utilize drug formulations

giving greater range of release rates and more precisely control drug delivery to the skin by utilizing different drug concentrations, different vehicles, different additives such as flux enhancers and different materials having different drug transference rates.

It is respectfully submitted that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. The Applicants respectfully submit that the referenced prior art fail to teach each and every limitation of the present invention, nor would there be any motivation to modify the prior art to arrive at the presently claimed invention.

The Applicants submit that the cited reference of Klose, et al. fails to teach or suggest each and every limitation of claim 1 as amended herewith. In particular, Klose, et al. fail to teach or suggest limitation of amended claim 1 of where the pharmaceutical preparation is a transdermal therapeutic system in the form of an active substance patch adhering to the skin, and the transdermal therapeutic system contains said combination in a solid polymer matrix the combinations.

The Klose, et al. reference relates to transdermal drug delivery systems comprising "at least one volatile liquid" as an essential component (paragraphs [0009] – [0021] and claim 1 of the '620 publication). Furthermore, Klose, et al. teach that these volatile liquid-containing drug delivery systems may be applied to the skin by means of an aerosol, spray, pump-back, brush, etc., implying that these systems are formulated as

liquid (or at least as a semi-solid) preparations. In contrast, the transdermal pharmaceutical preparations as defined by present claim 1 are in the form of an active substance patch, and the active substance combination is contained in a solid polymer matrix.

In view of the above, Klose, et al. fail to teach each and every limitation of the presently claimed invention and there would be no motivation for one skilled in the art to have modified the reference to arrive at the presently claimed invention. Withdrawal of this rejection is requested.

Turning now to the Carrara, et al. reference, it is noted that the reference was published on September 27, 2007 based on an application filed May 31, 2007 and which was (1) a continuation-in-part of Application Serial No. 11/634,005 filed on December 4, 2006, which was a continuation of Application Serial No. 10/343,570 filed on May 19, 2003 (now Patent No. 7,214,381) and which was filed as International Application No. PCT/EP01/09007 filed on August 3, 2001, (2) a continuation-in-part of Application Serial No. 11/371,042 filed on March 7, 2006, which was a continuation of Application No. PCT/EP04/11175 filed on October 6, 2004, and (3) claims the benefit of Provisional Application No. 60/510,613 filed on October 10, 2003. In turn, the present application was filed based on International Application No. PCT/EP04/009136 filed on August 14, 2004, with priority to German Application Serial No. 10338174.0 filed on August 20, 2003.

It is first noted that a certified English translation of the German priority application is enclosed herewith. Thus, the priority date of August 20, 2003 is perfected

and should be considered in the present analysis. In turn, it is submitted that the priority date of August 20, 2003 effectively pre-dates the provisional application filing date of October 10, 2003 of Carrara, et al. In this analysis, Carrara, et al. should be removed as a prior art reference.

The Applicants also respectfully submit that the '007 International Application (WO 02/11768) of Carrara, et al. does not support the '379 publication for purposes of prior art. WO '768 does not teach the anti-Parkinson agents recited in paragraph [0068] of the '379 publication (as noted by the Examiner in the Office action, page 4 – "Mixtures of the disclosed agent are also disclosed as suitable for use (paragraph 0068)." WO '768 merely discloses the generic term "antiparkinsonians" (see, for example, page 11 of WO '768, a copy of which is enclosed). In this regard, it is also submitted that the WO '768 does not support the teachings of the '379 publication and thus Carrara, et al. '379 is not a valid prior art reference under this analysis either.

In view of the above, it is respectfully requested that Carrara, et al. be removed as prior art and that this rejection (and the rejection of the claims based on Carrara, et al. in view of Andriola, et al.) should be withdrawn.

In view of the above, the Applicants respectfully request that the obviousness rejections be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art

references, the Applicants strongly urge that the obviousness-type rejection and anticipation rejections be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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